EUROPEAN COMMISSION

Brussels, 19.3.2012
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COMMISSION IMPLEMENTING DECISION

of 19.3.2012

transferring and amending the marketing authorisation granted by Decision C(2000)1407 for "PegIntron - Peginterferon alfa-2b", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH AND DUTCH TEXTS ARE AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 6 thereof,

Having regard to the application submitted by Schering Plough Europe on 28 January 2012 under Article 3 of Regulation (EC) No 2141/96,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[3], and in particular Article 17(2) thereof,

Having regard to the notification submitted by Schering Plough Europe, under the second subparagraph of Article 14(1) of Regulation (EC) No 1234/2008,

Whereas:

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 286, 8.11.1996, p. 6.
3 OJ L 334, 12.12.2008, p. 7.

(1) The medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under the number EU/1/00/131/001-050 and authorised by Commission Decision C(2000)1407 of 25 May 2000, remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency has given a favourable opinion,

(5) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on a minor variation notified between 12 December 2011 and 24 February 2012.

(6) The marketing authorisation should be updated and Decision C(2000)1407 of 25 May 2000 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

(7) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2000)1407 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2000)1407 of 25 May 2000 to Schering Plough Europe for the medicinal product "PegIntron - Peginterferon alfa-2b", entered in the Community register of medicinal products under No(s) EU/1/00/131/001-050, is transferred to Merck Sharp & Dohme Limited.

Article 2

Decision C(2000)1407 is amended as follows:

1) The following notification for a minor variation is added to the marketing authorisation:

Application number	Scope (EU numbers affected)

[4] OJ L 311, 28.11.2001, p. 67.

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) All the operations resulting from this transfer must be completed by 1 October 2012 at the latest.

Article 4

This Decision is addressed to:
1. Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom
and
2. Schering Plough Europe, Clos du Lynx 5, 1200 Bruxelles, Belgique – Lynx Binnenhof 5, 1200 Brussel, België.

Done at Brussels, on 19.3.2012.

For the Commission
Paola TESTORI COGGI
Director-General